PART IV

Section 1—C

GENERAL STATUTORY RULES AND STATUTORY ORDERS ISSUED BY THE CENTRAL GOVERNMENT AND ORDERS MADE BY THE PRESIDENT AND REPUBLISHED BY THE STATE GOVERNMENT.

NOTIFICATION.

(LAW DEPARTMENT).

No. LAW 115 LCR 67, dated Bangalore, 2nd August 1967.

Ordered that the Drugs and Cosmetics (First Amendment) Rules, 1967, published in S.O. No. 2369, dated 7th July, 1967, which has been published in the *Gazette of India*, Extraordinary Part II, Section 3, sub-section (ii), dated the 15th July 1967 be republished in the *Mysore Gazette*, for general information.

By Order and in the name of the Governor of Mysore,

H. K. ANANTHASUBBA RAO,
Under Secy. to Govt., L. D.

78

GOVERNMENT OF INDIA.

MINISTRY OF HEALTH & FAMILY PLANNING

(Department of Health)

New Delhi, the 7th July 1967.

S.O. **2369.**—In exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and

Cosmetics Rules, 1945, the same having been previously published as required by the said sections, namely :—

1. These rules may be called the Drugs and Cosmetics (First Amendment) Rules, 1967.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule F, after Part XII-A the following Part shall be inserted, namely :—

'PART XII-B'

Equipment and Supplies required for a Blood Bank

Blood Donor Room :

A. *Equipment.*—The blood donor room shall be air conditioned.

1. *Donor beds or tables* —The top of the bed or the table shall be padded with heavy felt or foam rubber and shall be covered with a washable plastic material The top of the bed or the table shall be sufficiently wide to give support to the arm of the donor. The table shall also be suitable to the requirements besides being comfortable.

2. Bed side stand.

3. Shaking apparatus or apparatus for mixing blood by technical staff.

4. Sphygmomanometer and Stethoscope.

5. Recovery bed of about 50 cm. in height.

6. Accessory item such as blankets, emesis basins, hemostats, donor set clamps, sponge forceps dressing jars, solution jars, waste cans and adjustable lamps.

B. *Blood collection supplies.*—The blood collection shall be done either by the closed method or by the gravity method. Donor sets with 16 S.W.G. 5 cm. needle, donor bottles (Pyrogen free), lancets for haemoglobin and pilot tubes shall be sterile and ready for being used. The needles shall be piercing needles made of stainless steel gauge 11×16 cm. or 26 cm. length depending upon the size of the bottle. When the gravity method is used the outlet needle must have a sterile cotton wool filter.

1. *Haemoglobin determination* :

(a) Copper sulphate solution, specific gravity 1·052

(b) Sterile lancets.

(c) Capillary tubing 1.3—1.4×65 mm or pasteur pipettes.

(d) Rubber bulbs for capillary tublngs.

(e) Sahli's Haemoglobinometer.

2. *Temperature and pulse determination* :

(a) Clinical thermometers.

(t) Equipment and material for aseptic cleaning and thermometer.

(;) Watch (fitted with a second hand needle).

3. Blood collection bottles—375 ml.

4. Blood collection sets.

5. Sterile pilot tubes for being attached to the flow bottle.

6. Hypodermic syringes 2 ml, needle of 26 s.w.g./1.5 cm.

7. Cotton gauze squares (5 cm.×5 cm.) medium cotton balls.

8. Alcohol 1.25 cm. adhesive tape (70 per cent); green soap or hexachloroprene liquid soap; Tincture Iodine and Injection of Procaine.

9. Paper napkins or towels.

C. *Canteen equipment*

Provision for serving refreshments to the donor after phlebotomy may also be made so that he may be kept for observation in the blood bank for any reactions.

D. *Emergency equipment* :

1. Small oxygen cylinder with mask; gauge and Pressure regulator.

2. Plasma and/or albumin (Human).

3. Sterile syringe and needle.

4. Sterile I.V. Infusion set.

5. Ampoules of Adrenaline. Injection of Calcium Gluconate, Injection of Atropine, Injection of Nikethamide and Injection of Noradrenaline; Distilled water.

6. Aspirin and Aromatic Water.

Laboratory

A. *Equipment* :

1. Refrigerators maintaining a temperature between 4° to 6°C. with a little deviation as possible in temperature.

2. Alarm system for alerting a person on duty in the event of very high deviation in temperature or failure of the machine.

3. Recording thermometer for refrigerator.

4. Charts and ink for recording thermometer.

5. Microscope, compound with low and high power objectives.

6. Centrifuges—Table model for blood grouping and cross matching.

7. Water-baths—one for 37°C and another for 56°C.

8. Rhviewing box. The surface of viewing glass shall not have 'hot spots' and its temperature shall not exceed 47°C.

9. Incubator, bacteriological for control cultures.

10. Mechanical shakers for serological tests for syphilis.

11. Hand lens for observing tests conducted in tubes.

12. Pipettes, serological, 1.0 ml. graduated in .001, .01, 0.2 ml.

13. Pipettes, Pasteur.

14. Glass slides, glass plates and/or porcelain deep wells or plates.

15. Test tubes, serological, 13×100 mm.

16. Precipitin tubes 6 mm × 50 mm.

17. Test tube racks.

18. 15 cm applicators and toothpicks.

19. Interval timer, electric or spring wound.

20. Equipment and materials for cleaning glassware adequately.

21. Shipping Containers.

B. Reagents :—

1. Standard Blood grouping sera, anti-A, and Anti-B and Anti-AB, all in double quantity and each of a different brand, or if from the same supplier, each supply should be of a different lot number.

2. Rh typing sera. All in double quantity and each of a different brand or if from the same supplier, each supply should be of a different lot number.

3. Reagents or serological tests for syphilis and positive sera fo controls.

4. Anti-human globulin serum (Coombs serum) for confirming crossmatches, determining Rh negative blood and performing antibody tests.

5. Albumin, human or bovine, 30% for tests requiring high protein concentration.

6. 0.9% saline.

7. Culture media and tubes.

8. Wax pencils and labels.

9. Detergents and other agents for cleaning laboratory glassware

General Supplies

1. Autoclave

2. Temperature recorder (The autoclave should be equipped with a temperature recording device which gives a record of the temperature and length of time for each sterilization).

Technical Staff

1. A medical graduate having experience in blood bank.

2. Registered nurse—one.

3. Blood bank technician having experience in blood grouping and serology work.

4. One Assistant.

5. One Attendant.

Accommodation for Blood Bank

Minimum total area should be about 100 square Meters and consisting of six rooms namely :—

1. Registration and medical examination room.
2. Blood Collection room.
3. Room for laboratory.
4. Room for sterilising and washing.

5. Refreshment room.

6. Room for keeping records and stores.

Label for whole blood

The label on the blood container should contain the following particulars, namely :—

1. The Serial number of the bottle.

2. The date on which the blood is drawn, and the date of expiry which shall not be more than 21 days from the date on which the blood is drawn.

3. The ABO group with the corresponding colour.

Colour Scheme for Labels

The following colour scheme for labels may be used for different groups.

Group	Colour of Label
O	Blue
A	Yellow
B	Pink
AB	White

4. The Rh group.

5. The total volume of fluid, the proportion of anticoagulant.

6. The contents should not be used if there is any visible evidence of deterioration.

7. Name of Blood Bank.

8. Address.

9. A filter must be used in administration equipment.

10. Keep continuously at 4° to 6°C.

11. Crossmatch before using.

Precautionary Measures :—

1. Administer without warming.

2. Shake gently before using.

3. Do not add other medication to the blood.

4. Check blood group on label and recipients group before administration.

5. Use a fresh, clean and sterile transfusion set to transfuse the blood.

6. Do not dispense without prescription.

NOTE.—The above requirements of Blood Bank are subject to modifications at the discretion of the Licensing Authority if he is of the opinion that having regard to the extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

[F. No. 1-17/62-D]

R. N. SINHA, Under Secy.